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| EXAMINER | |
|---|---|
| EPPERSON, JON D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1639 | |

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/943,138 | DYER, WALLACE K. | |
| | Examiner | Art Unit | |
| | Jon D Epperson | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4,7-11,13,15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) *15 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-11,13 and 20-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

1. The Response filed November 29, 2004 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Status of the Claims*

3. Claims 1, 4, 7-11, 13, 15 and 17-29 were pending. Applicants amended claims 1, 4, 15 and 22. No claims were added or canceled. Therefore, claims 1, 4, 7-11, 13, 15 and 17-29 are still pending.

4. Claims 15 and 17-19 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim.

5. Therefore, claims 1, 4, 7-11, 13 and 20-29 are examined on the merits in this action.

### Withdrawn Objections/Rejections

6. All rejections are maintained and the arguments are addressed below.

## Outstanding Objections and/or Rejections

### *Claims Rejections - 35 U.S.C. 102*

7. Claims 1, 4, 7-11, 13, and 20-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (US Patent No. 5,336,263) (Date of Patent is **August 9, 1994**) as evidenced by the Polymer Products from Aldrich Reference (of record) (**Please note**: that MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent).

For ***claims 1, 4, 7 and 22***, Ersek et al. (see entire document) disclose biphasic compositions for the treatment of urological and gastric fluid disorders (e.g., see abstract), which anticipate claims 1, 4, 7 and 22. For example, Ersek et al. disclose biocompatible micronized textured polyethylene particles having a size greater than sixty microns (e.g., see abstract; see also column 3, lines 23-26, "The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 80 > 60]"; see also paragraph bridging columns 5-6, "For soft tissue ... [a] desirable material for the textured particles ... [is] polyethylene"). In addition, Ersek et al. disclose various physiological carriers including polyvinylpyrrolidone (e.g., see column 3, lines 37-53, "Examples of appropriate physiologic vehicles [i.e., physiological carriers] are ... polyvinylpyrrolidones").

The Examiner further notes that the limitations in the preamble claiming a mechanically stable biphasic injectable composition for "soft tissue augmentation" and in the last line of the claim "wherein the composition is injected into soft tissue" are

*intended use* recitations that merely recite the purpose of the process or the intended use of the structure and thus have not been accorded any patentable weight (e.g., see MPEP 2111.02: A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481. Also, "[i]n a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art." *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In addition, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01.

For ***claims 8-11 and 24-27***, Ersek et al. do not disclose any K values for the polyvinylpyrrolidones (PVP) used therein; however, Ersek et al. disclose a polyvinylpyrrolidone with a molecular weight of 13,700 (e.g., see Example 2), which would inherently possess a K between 13-19 (e.g., see Polymer Products from Aldrich Reference, page 5, Table III, citing "GAF(ISP) Technical Bulletin 2302-203 SM-1290,

"PVP polyvinylpyrrolidone Polymers", wherein the relationship between the K-value and the molecular weight and/or intrinsic viscosity of PVP has been calculated and clearly shows that that the K value for the PVP is in the range of 13-19 because 13,700 $M_w$ falls within the ~ 12,000 $M_w$ range). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claims 13 and 23***, Ersek et al. disclose an "approximately" 3:2 ratio by weight carrier to particles (e.g., see column 9, lines 25-27, "The mixture utilized was approximately 38% by weight of the polymer particles and 62% of the gel material [i.e., 62% gel / 38% particles = 1.6, which is "approximately" 1.5 or a 3/2 ratio by weight]"; see also paragraph bridging columns 5-6 wherein Ersek et al. disclose that polyethylene can be substituted for poly(dimethylsiloxane) disclosed in Example I; see also column 8, lines 61-63 wherein Ersek et al. disclose that this "ratio" represents a mere design choice).

For ***claims 20-21 and 28-29***, Ersek et al. disclose particles having a size greater than 100 microns (e.g., see column 3, lines 23-26, "The textured micro particles have a nominal unidimensional measurement ... between about 80 and 600 microns [i.e., 600 > 100]").

***Response***

8. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue, "... there is no teaching in Ersek et al. that polyethylene is '[a] desirable material' for soft tissue ... Ersek et al. specifically teach that polyethylene is not used for soft tissue augmentation, but that soft elastomers are used ... The further rejection of dependent Claims 8-11 ... as being anticipated by Ersek et al. ... does not lessen the teaching away of Ersek et al. [mentioned above]" (e.g., see 11/29/04, pages 1-2).

This is not found persuasive for the following reasons:

In response to Applicants' argument that their compositions are used for "soft tissue augmentation" and/or are "injected into soft tissue" (e.g., see newly amended claim 1), the Examiner contends that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the prior art of Ersek et al. disclose a composition comprising (1) a biocompatible micronized textured polyethylene particles and (2) a physiological carrier (e.g., see amended rejection above) and, as

a result, it does not matter whether Ersek et al. teach the intended use for soft tissue augmentation or not (i.e., Applicants' arguments are moot).

In addition, the Examiner notes that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, Applicants' intended use of "soft tissue augmentation" occurs in the preamble and thus is not afforded any patentable weight. Furthermore, the Examiner contends it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) (" [M]ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex , 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 162

(CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); *In re Benner*, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Thus, even if assuming arguendo that Applicants' soft tissue augmentation represents a "new use" for the old polyethylene particles/carrier the claimed invention would still not be patentable in accordance with the cases outlined above.

Accordingly, the 35 U.S.C. § 102(b) rejection cited above is hereby maintained.

## New Rejections

### *Claims Rejections - 35 U.S.C. 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1, 4, 7, 13 and 20-22, 28, 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Bisson (FR 2785811) (Publication date is **May 19, 2000**).

For ***claims 1, 4, 7, 20-22, 28, 29***, Bisson (see entire document) discloses compositions comprising porous microparticles and/or a suspension agent used for soft tissue augmentation (e.g., see Bisson translation, page 1, paragraph 1; see also claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"), which anticipates the claimed invention. For example, Bisson

discloses biocompatible micronized textured polyethylene particles with a size greater than 60 microns (e.g., see Bisson translation, page 4, paragraphs 1-2, "The material which constitutes the microparticles will be ... polyethylene"; see also claim 3, "Composition ... characterized in that the particles have a spherical or ovoid shape with a diameter greater than approximately 10 μm, preferably 30-100 μm [i.e., these are "micronized" particles]"). In addition, Bisson discloses a "textured" microparticles (e.g., see Bisson translation, claim 1, "Composition comprising porous microparticles [i.e., has a "textured" surface] whose pore diameter excludes the penetration of figured elements having a molecular weight of more than 1000 kilodalton"). Finally, Bisson discloses a physiological carrier (e.g., Bisson translation, claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"; see also page 5, see also claim 12, "Composition according to any one of Claims 8-10, characterized in that the suspension agent is a liquid or a gel chosen from the polymers of substituted or unsubstituted acrylamide, of vinylpyrrolidone, of hydroxyalkyl acrylate, or the copolymers of substituted or unsubstituted acrylamide and of another molecule bearing a positive electric charge, such as a quaternary ammonium cationic monomer"). The examiner also notes that the above composition is used for "soft tissue augmentation" and is explicitly injected into soft tissue (e.g., see page 1, paragraph 1, "The present invention concerns compositions comprising porous microparticles and/or a suspension agent ... usable for implantation in a tissue, in particular to increase the volume of this tissue ("soft tissue augmentation"), notably in view of correcting in a lasting manner a deficit in the appearance or the function of this tissue or organ").

***Conclusion***

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
February 24, 2005